April 25, 2022

Veru Announces Oral Late-Breaking Presentation of Phase 2 Data of Sabizabulin for the Treatment of Hospitalized Severe COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome at the 32nd European Congress of Clinical Microbiology & Infectious Diseases

MIAMI, April 25, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a biopharmaceutical company, today announced that results from the randomized placebo-controlled Phase 2 study of daily, oral sabizabulin in patients with severe COVID-19 at high risk for acute respiratory distress syndrome (ARDS) were presented at the 32nd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) being held in Lisbon, Portugal on April 23-26, 2022.

“The data observed in this small Phase 2 study are quite dramatic and provided the support for pursuing sabizabulin in the Phase 3 setting,” said Michael Gordon MD, Chief Medical Officer, Honor Health Research and Innovation Institute, one of the lead investigators on the study. “We need a safe drug that can be utilized in the most severely ill COVID-19 patients to save lives and sabizabulin appears to meet this need.”

“We are very excited about the clinically meaningful reduction in deaths in hospitalized COVID-19 patients at high risk for ARDS and death being presented from this Phase 2 study. The clinically meaningful and statistically significant reduction in deaths in this high risk population was confirmed in a Phase 3 COVID-19 study which was stopped for overwhelming efficacy based on a planned interim analysis, said Mitchell S. Steiner MD, Chairman, President and Chief Executive Officer of Veru Inc. “Sabizabulin appears to have the ability to prevent deaths in the sickest of COVID-19 patients and we are working diligently to bring sabizabulin to these patients.”

The oral, late-breaking presentation was given during Session 12 – Current treatment approach to COVID-19 and was held on April 23, 2022 at 11:15 AM – 1:15 PM EDT.

Abstract number: 4407
Presentation title: Phase 2 study of oral sabizabulin for the treatment of SARS-CoV-2 in hospitalized patients at high risk for ARDS
Presentation being given by: Michael Gordon MD, Chief Medical Officer at HonorHealth Research and Innovation Institute in Scottsdale, Arizona

Phase 2 Trial Design: Veru conducted a double-blind, randomized, placebo-controlled Phase 2 clinical trial evaluating oral, once-a-day dosing of sabizabulin versus placebo in approximately 40 hospitalized COVID-19 patients who were at high risk for ARDS. The trial was conducted in five sites across the United States. Patients hospitalized with documented evidence of COVID-19 infection and at high risk for ARDS were enrolled. Subjects received daily oral dosing of sabizabulin or placebo, as well as standard of care for 21 days or until released from hospital. The primary efficacy endpoint was the proportion of patients alive without respiratory failure at Day 29. Respiratory failure was defined as endotracheal intubation and mechanical ventilation, extracorporeal membrane oxygenation, high-flow nasal cannula oxygen delivery, noninvasive positive pressure ventilation, and/or clinical diagnosis of respiratory failure with initiation of none of these measures only when clinical decision making is driven solely by resource limitation.

Results: In this cohort of patients with severe COVID-19, sabizabulin treatment resulted in an 82% relative reduction in deaths (p=0.0442) in the ITT population. Further, sabizabulin treatment resulted in a reduction in mean days in the ICU from 9.6 ± 12.40 days in the placebo group to 2.6 ± 5.78 days (p=0.0261) in the sabizabulin treated group, a 73% relative reduction in the mean days in the ICU. Similarly, there was a reduction in mean days on mechanical ventilation from 5.1 ± 11.24 days in the placebo group to 1.2 ± 6.06 days (p=0.1437), a 78% relative reduction in days on mechanical ventilation. Sabizabulin was safe and well tolerated with no treatment related adverse events observed on the study.

The severity of the COVID-19 infection at baseline, as measured by the WHO scale, was a significant predictor of patient outcomes. The disease severity at baseline was not different between the treatment groups.

About Veru Inc.
Veru is a biopharmaceutical company with a principal focus on developing novel medicines for COVID-19 and other viral and ARDS-related diseases and for the management of breast and prostate cancers.

A double-blind, randomized, placebo-controlled Phase 3 COVID-19 clinical trial was conducted in approximately 210 hospitalized COVID-19 patients with moderate to severe COVID (WHO 4) at high risk for ARDS and death. The primary endpoint was the proportion of deaths by Day 60. Based on a planned interim analysis of the first 150 patients to complete 60 days of followup, the Independent Data Monitoring Committee unanimously halted the study for overwhelming efficacy and safety. Treatment with sabizabulin 9mg once daily, an oral, first-in-class, new chemical entity, cytoskeleton disruptor that has dual anti-inflammatory and antiviral properties, resulted in a clinically meaningful and statistically significant 55% relative reduction in deaths. The Company is seeking FDA emergency use authorization and an advance purchase agreement from the US Government. FDA granted Fast Track designation to the Company's COVID-19 program in January 2022.

The Company's late-stage breast cancer development portfolio comprises enobosarm, a

selective androgen receptor targeting agonist, and sabizabulin.

Current studies on the two drugs include:

- Enrolling Phase 3 ARTEST study of enobosarm in androgen receptor positive, estrogen receptor positive, and human epidermal growth factor receptor two negative (AR+ ER+ HER2-) metastatic breast cancer with AR ≥ 40% expression (third-line metastatic setting), and which has been granted Fast Track designation by the FDA.

- Enrolling Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) combination in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% expression (second-line metastatic setting). The Company and Eli Lilly and Company have entered into a clinical study collaboration and supply agreement for the ENABLAR-2 study. Lilly will supply Verzenio® (abemaciclib).

- Planned Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% expression (third-line metastatic setting).

Veru's late-stage prostate cancer portfolio comprises sabizabulin, VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

Current studies on these drugs include:

- Enrolling Phase 3 VERACITY study in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy.

- Enrolling Phase 2 dose-finding study of VERU-100 in advanced hormone sensitive prostate cancer.

- Planned Phase 2b study of zuclomiphene citrate to treat hot flashes in men with advanced prostate cancer undergoing androgen deprivation therapy.

Veru also has a commercial sexual health division - Urev, the proceeds of which help fund its drug development programs, comprised of 2 FDA approved products:

- ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia, for which commercialization launch plans are underway.

- FC2 Female Condom® (internal condom), for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections which is sold in the U.S. and globally.

Forward-Looking Statements
The statements in this release that are not historical facts are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements regarding: whether and when the Company will meet with FDA or receive an emergency use authorization or any approval from FDA for sabizabulin for certain COVID-19 patients; whether and when sabizabulin will become an available treatment option for certain COVID-19 patients; whether the Company will have sufficient supply of sabizabulin to meet demand, if an emergency use authorization

or other approval is granted; whether the Company will secure any advance purchase agreement with the U.S. government; whether the current and future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates and companion diagnostic; whether the drug candidates will be approved for the targeted line of therapy; the anticipated design and scope of clinical studies and FDA acceptance of such design and scope; whether any regulatory pathways, including the accelerated Fast Track designations, to seek FDA approval for sabizabulin, enobosarm or any of the Company's drug candidates are or continue to be available; whether the expected commencement and timing of the Company's clinical studies, including the Phase 3 ENABLAR-2 study, the sabizabulin monotherapy Phase 2b clinical study for 3rd line treatment of metastatic breast cancer, the Phase 2 registration clinical study for VERU-100, and the development of the companion diagnostic will be met; when clinical results from the ongoing clinical studies will be available, whether sabizabulin, enobosarm, VERU-100, zuclomiphene, and ENTADFI will serve any unmet need or, what dosage, if any, might be approved for use in the US or elsewhere, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, and the timing of the Company's submissions to FDA and FDA's review of all such submissions; whether any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm, VERU-100 or other drug candidates will be replicated in the current and planned clinical development program for such drug candidates and whether any such properties will be recognized by the FDA in any potential approvals and labeling; whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; and whether and when ENTADFI will be commercialized successfully. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the development of the Company's product portfolio and the results of clinical studies possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical studies and the ability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development; the timing of any submission to the FDA and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities possibly taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the Company's existing products and any future products, if approved, possibly not being commercially successful; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical studies, supply chain and other third-party providers, commercial efforts, and business development operations; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to successfully commercialize any of its products, if approved; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential

regulatory complexity, and development costs; the Company's ability to protect and enforce its intellectual property; the potential that delays in orders or shipments under government tenders or the Company's U.S. prescription business could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; the Company's reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; the concentration of accounts receivable with our largest customers and the collection of those receivables; the Company's production capacity, efficiency and supply constraints and interruptions, including potential disruption of production at the Company's and third party manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's and third party facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; costs and other effects of litigation, including product liability claims; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed from time to time in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the fiscal year ended September 30, 2021 and subsequent quarterly reports on Form 10-Q. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors. The Company disclaims any intent or obligation to update these forward-looking statements.

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